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degussa.

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October 6, 2003

Document Processing Center
EPA East (Mail Code 7407M)
Attn: TSCA Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20460-0001

Contain NO CBI



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Dear Madam or Sir:

Enclosed are summaries of 43 toxicology studies conducted by or for Degussa AG in Germany. These summaries reflect the results of one or more studies conducted on each of 21 chemical substances. Twelve of the summaries include information which we are reporting pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The remaining nine studies include information that suggests that the test substance may cause adverse health or environmental effects at high exposure levels. However, because these substances are manufactured or imported in the United States only in limited quantities for use as intermediates in chemical synthesis, they do not currently present a substantial risk to health or the environment. We are therefore submitting them to EPA on a "For Your Information" basis.

These 21 summaries are being submitted pursuant to a data review that Degussa is conducting in connection with its implementation of a new computer system that will permit Degussa Corporation in the United States to access data previously available only to Degussa AG in Germany. Recognizing that a large number of these studies might need to be reported under TSCA 8(e), Degussa proactively contacted EPA in mid 2002 and proposed to review the studies in batches and submit any 8(e) reportable data to EPA within 15 business days (now 30 calendar days) of completing its review of each batch. Degussa estimated that the review would take approximately six months to complete. In a memorandum received in November 2002, the Agency concurred in this approach.

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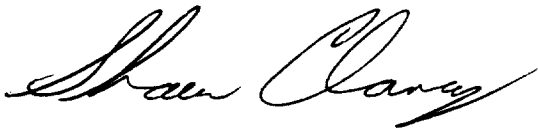
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These studies were made available to Degussa Corporation in April 2003. Degussa's toxicologists in Germany have reviewed more than 750 studies on approximately 100 chemical substances and prepared English summaries of the results of 70 studies for evaluation by scientists in the United States for reporting under TSCA Section 8(e). This submission represents Degussa's review of this first batch of studies by our scientists in Germany and the United States, which was completed on September 12, 2003. Degussa has determined that approximately 1500 studies remain to be reviewed. As we have separately informed Ms. Ann Pontius of the Toxics and Pesticides Enforcement Division, we estimate that the review of the remaining studies will take an additional nine months to complete. We will continue to submit reportable and FYI studies to EPA as our review of subsequent batches is completed.

We appreciate your attention to this matter and request your comments regarding the approach we have taken. Please do not hesitate to call me at (973) 541-8047 if you have any questions or wish to discuss this matter further.

Best regards,

A handwritten signature in cursive script, reading "Shaun Clancy".

Shaun F. Clancy, Ph.D.

1 **Date** 10/13/2001

Sender's Name S. Clancy **Phone** 973 541-8042

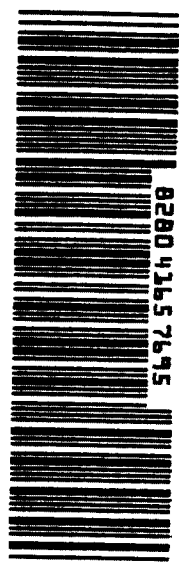
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2 **Your Internal Billing Reference**

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Memo

To: File
From: Shaun Clancy
CC:
Date: 10/06/03
Re: TSCA 8(e) Review – 826-36-8

Two endpoints were provided by Fine Chemicals for 826-36-8 Triacetoneamine

- Acute Oral Tox
- Acute Eye Irritation

This chemical is used as an intermediate in organic synthesis and is not expected to be used in a way such that human exposure outside of an industrial setting will occur or that an environmental exposure will result. Appropriate Personal Protective Equipment is specified in the MSDS as is warnings not to allow the substance to be released. When used correctly the risk of human and environmental exposure is minimal.

The result of the eye irritation study is not surprising given that the chemical is a secondary amine and is not reportable. The results of the oral toxicity test included indications of neurotoxicity. Given the high dose, other toxic effects and the reversibility of the possible neurotoxic effects, it is not clear that the potential effects are due to neurotoxicity. It is concluded that these effects may be reportable under TSCA 8(e) and will be submitted.

Contains No CBI

degussa.**Fax**

To: Shaun Clancy
S-SR-US-EHS

Fax-No. Recipient: 001-973 541 8040

Pages (total): 10

cc: Dr. W. Mayr/FC-TME-CSM

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Fine chemicals
Chemicals Safety
Management

FC-TME-CSM/Dr.Jbi/sch

Initial notice of Information for possible TSCA 8e submission
Triacetoneamine, CAS No. 826-36-8

Dear Shaun,

August, 6 2003

Please find attached data obtained for the above mentioned substance for assessment of possible TSCA reportability.

I am at your disposal for any further questions.

English translations of the summaries and/or results of the studies are attached.

Best regards


Sylvia Jacobi

degussa.**Initial Notice of Information to be assessed for Possible TSCA,
Sec. 8e Reporting**

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Fine chemicals
Chemicals Safety
Management

August 6, 2003

Name / Trade name of the Substance	Triacetoneamine
CAS-No.:	826-36-8

Human Health Effects**Environmental Effects**

Degussa-Study-No.:	85-0254-DKT 85-0258-DKT
Other Source of Information:	

Summary of Adverse Effects

Acute oral toxicity study in rats

Source Degussa AG, unpublished report No. 85-0254-DKT

Guideline OECD 401, non-GLP

Doses of 1000, 1250, and 1580 mg/kg bw were administered undiluted (Volume 1.08 to 1.706 ml/kg bw) to groups of 5 male and 5 female Wistar rats.

The LD50 was 1330 mg/kg bw. Symptoms were observed in all animals of all dose groups. Symptoms indicative of possible neurotoxicity included slight tremor and staggered gait, and increased reactivity occurring about 30 min p.a.. Later on sedation, axia, laboured respiration, hypothermia, abdominal position (at times), convulsions, half closed and closed eyes were observed as additional symptoms. The symptoms were reversible in the low and mid dose group within 48 h, in the high dose group within 6 days.

Macroscopic findings: Hyperemia of the gastric and small intestinal mucosa, congestion of liver and spleen. One animal had a pale kidney and a whitish discoloration of the pancreas. Animals that were sacrificed at the end of the observation period showed in some cases hyperemia of the mucosa of the stomach and small intestine, and dark spots on the kidneys.

Acute eye irritation study in rabbits

Source: Degussa AG, unpublished report No. 85-0258-DKT

Guideline: OECD No. 405 (1981), non-GLP.

degussa.

The study was performed with one animal. 100 mg of the test substance was applied to the conjunctival sac of one eye. The eye was rinsed after 72 h with physiological saline. Corneal opacity grade 1 was observed after 1 and 24 h, grade 2 after 48 and 72 h, the iris was redenned (irritation index of 1 1 to 72 h), severe conjunctival erythema (grade 3) was observed at all time points. Additonally necrosis of the conjunctival sac and bleeding and detachment of the mucous membranes was observed. Due to the severe effects on the conjunctivae the study was terminated after 72 h. Due to the described effects the substance can be regarded as corrosive to eyes.

Page 02 of 02

Nature and Extent of Risk Involved:

Risk of incapacitation due to severe irritation and corrosion to the eyes.
Possible neurotoxic effects after oral ingestion of relatively high doses.

Information by	Date:
Dr. Sylvia Jacobi	August 6, 2003

HÜLS AKTIENGESELLSCHAFT
- Toxicology -

Copy No. 3

Marl, Nov. 8, 1985

Report No. 0489
Acute Oral Toxicity of
Triacetonamine
in Rats

by

P. Mürmann

Until the results contained in this study are published, they may be used only with the consent of HÜLS AG, PsT. Reproduction of this report – even in excerpts – is not permitted.

Degussa-Hüls AG – REG No.
85 - 0254 - DKT

- 1 -

I Summary:

An acute oral toxicity determination on male and female rats showed that the LD₅₀ value of triacetoneamine is about 1,330 mg/kg body weight. Only one of the treated animals had intoxication symptoms for up to 6 days. The body weight development was not influenced. The dissections at the end of the study revealed hyperemia of the gastric and small-intestinal mucosae and dark spots on the kidneys of some animals.

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V The results of the study are shown in the following table.

Triacetoneamine
Acute oral toxicity (LD₅₀) for rats

Dose (mg/kg)	Sex	Toxicological Result	Number of Hours Within Which Death Occurred	LD ₅₀ (mg/kg)
1000	male female	0/5/5 1/5/5	3.5	1330 (1161-1524) Gradient function S = 1.25
1250	male female	1/5/5 4/5/5	24	
1580	male female	4/5/5 3/5/5	120	

*Number of animals that died / number of animals with symptoms / number of animals used.

Body Weight Development (mean values) in g

Dose (mg/kg)	Before Administration (fasting)	24 Hr. After Administration	1 Wk. After Administration	2 Wks. After Administration	Weight Gain
1000	105.4	96.2	134.9	168.3	62.9
1250	106.5	100.8	135.2	171.8	65.3
1580	119.2	107.0	138.7	170.0	50.8

The treatment had no influence on the body weight development. About 30 min after the treatment, the animals exhibited ruffled fur, timidity, slight tremor and staggering. Subsequently, slight sedation and ataxia, difficulty breathing, hypothermia, temporary abdominal position, twitching and half-closed or closed eyes. Whereas the animals of the lower two dose groups were free of symptoms after 48 hr, one animal of the highest dose group showed a slightly ruffled fur and squatting position for up to 6 days. The post-mortem dissections showed hyperemia of the gastric and small-intestinal mucosae and congestion of the liver and spleen. One animal exhibited a bright-colored kidney and a whitish decoloration of the pancreas. After the end of the experiment, dissections showed hyperemia of the gastric and small-intestinal mucosae and dark spots on the kidneys in some animals.

Author and Study Director

[Signature]

(Dr. P. Mürmann)

Veterinary Specialist in Pharmacology and Toxicology

TO: [illegible]
FROM: [illegible]

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HÜLS AKTIENGESELLSCHAFT
- Toxicology -

Copy No. 3

Marl, 10/23/1985

Report No. 0491
Test of Acute Irritant Action of
Triacetoneamine
on Eyes and Conjunctivae

by

P. Mürmann

Until the results contained in this study are published, they may be used only with the consent of HÜLS AG, PsT. Reproduction of this report – even in excerpts – is not permitted.

Degussa-Hüls AG – REG No.
85 - 0258 - DKT

- 1 -

I Summary

Triacetoneamine was administered undiluted in the eye and under the eyelid of a male rabbit to test the acute irritant action on the eye and conjunctiva.

Result:

Triacetoneamine showed an irritation index of 38/110 (1 animal!) and detachment of the conjunctiva on the eye and conjunctiva of a rabbit, indicating a corrosive action.